

MAR 15 2001

**Summary of Safety and Effectiveness Information**

The assigned 510(k) number is: K003501

**Submitter's Name:** Rebecca S. Ayash  
Dade Behring Inc.  
Building 500, Mailbox 514  
P.O. Box 6101  
Newark, DE 19714-6101  
Phone: (302) 631-6276  
FAX: (302) 631-6299

**Date of Preparation:** 11/10/00

**Device Name:** N Protein Standard UY  
**Classification Name:** Calibrator, secondary  
**Predicate Device:** N Protein Standard UY (K991705)

**Device Description:** N Protein Standard UY is a lyophilized standard prepared from human urinary proteins in polygeline and preservative. It is intended to establish reference curves for the quantitative determination of  $\alpha_1$ -microglobulin by immunonephelometry with BN™ Systems and is being modified to add the analyte cystatin C.

**Intended Use:** N Protein Standard UY is intended for preparing reference curves for the immunonephelometric determinations of  $\alpha_1$ -microglobulin and cystatin C using BN™ Systems.

**Comparison to Predicate Device:**

	N Protein Standard UY (K991705)	Modified N Protein Standard UY
Intended Use	Calibrator	Calibrator
Analytes	Human $\alpha_1$ – microglobulin	Human $\alpha_1$ – microglobulin and cystatin C
Matrix	Polygeline and preservative	Polygeline and preservative
Form	Lyophilized	Lyophilized

**Device Performance Characteristics:**

**Stability:**

Stability was evaluated according to Dade Behring protocol and the standard was found to be stable for at least 24 months at +2° to +8° C, as originally packaged and for at least 14 days at +2° to +8° C, once reconstituted.

**Conclusion:** N Protein Standard UY is equivalent to the current N Protein Standard UY (K991705). The modified N Protein Standard UY differs only in the inclusion of the analyte cystatin C. Both products are intended to be used to establish reference curves for BN™ systems.

BN™ is a trademark of Dade Behring Marburg GmbH



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 15 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Rebecca S. Ayash  
Director, Regulatory Affairs, Biology  
Dade Behring Inc.  
P.O. Box 6101  
Newark, DE 19714

Re: K003501  
Trade Name: N Protein Standard UY  
Regulatory Class: II  
Product Code: JIT  
Dated: February 1, 2000  
Received: February 2, 2001

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

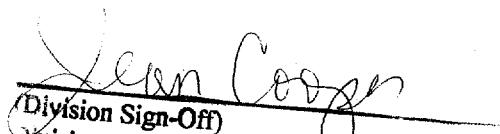
## Indications for Use Statement

510(k) Number (If known) K003501

Device Name: N Protein Standard UY

### Indications for Use:

N Protein Standard UY is intended for preparing reference curves for the immunonephelometric determinations of  $\alpha_1$ -microglobulin and cystatin C using BN™ Systems.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K003501

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

Over-The-Counter-Use ☐  
(Optional Format 1-2-96)